

Notice of Allowability

Application No.

09/857,325

Examiner

Q. Janice Li, M.D.

Applicant(s)

ELLIOTT ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/7/06
2. ☒ The allowed claim(s) is/are 212-215, 222 and 225-236.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Q. Janice Li, M.D.
Primary Examiner
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DETAILED ACTION

This action is in response to the amendment filed April 7, 2006. Claims 110-211, 216-221 have been cancelled. Claims 212, and 214 have been amended. Claims 222-236 are newly submitted. Claims 212-215, 222-236 are pending and under current examination. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office action mailed on 11/2/05 are withdrawn in view of the amendments.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Moore on May 1, 2006.

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment that places this application in condition for allowance. During a telephone conversation conducted on 4/20/06, Applicant requested an extension of time for one MONTH(S) and authorized the Commissioner to charge Deposit Account No. 08-1349 the required fee of \$60.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to

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applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The claims have been amended as follows:

212. (Currently Amended) A method of preparing a xenotransplantable islet comprising in sequential order the steps of:
- (i) harvesting the pancreas of a piglet, said piglet having an age of between -20 to +10 days relative to full-term gestation,
 - (ii) exposing said harvested pancreas to nicotinamide,
 - (iii) exposing said harvested pancreas to ~~a trauma-protecting amount of~~ lignocaine; and
 - (iv) extracting pancreatic β islet cells from said harvested pancreas and simultaneously contacting said pancreatic β islet cells with a quinolone antibiotic, wherein said method results in said xenotransplantable islet.
213. (Currently Amended) A method of preparing a xenotransplantable porcine islet, said method comprising in sequential order at least the steps of:
- (i) harvesting a pancreas of a piglet, the piglet having an age of between -20 to +10 days relative to full-term gestation,
 - (ii) exposing said harvested pancreas to ~~an effective amount of~~ nicotinamide, and
 - (iii) extracting pancreatic β islet cells from said harvested pancreas and

simultaneously contacting said pancreatic β islet cells with ~~an effective amount of~~ ciprofloxacin; wherein said method results in said xenotransplantable porcine islet.

214. (Currently Amended) A method of preparing a xenotransplantable porcine islet, said method comprising in sequential order at least the steps of:

- (i) harvesting a pancreas of a piglet, said piglet having an age of between -20 to +10 days relative to full-term gestation,
- (ii) exposing said harvested pancreas to ~~an effective amount of~~ nicotinamide, and
- (iii) extracting pancreatic β islet cells from said harvested pancreas and simultaneously contacting said pancreatic β islet cells with ~~a trauma-protecting amount of~~ lignocaine, wherein said method results in said xenotransplantable porcine islet.

In claim 215, the phrase --in sequential order-- was inserted after "comprising" in line 2.

222. (Currently Amended) A method of preparing a xenotransplantable porcine islet comprising in sequential order the steps of:

- (i) harvesting the pancreas of a piglet, the piglet having an age of between -20 to +10 days relative to full term gestation,

~~(ii) exposing the harvested pancreas to nicotinamide,~~

~~(iii) exposing the harvested pancreas to the trauma-protecting agent lignocaine,~~

and

(ii) exposing the harvested pancreas to a trauma-protecting agent lignocaine,

(iii) exposing the harvested pancreas to nicotinamide, and

(iv) extracting pancreatic β islet cells from the harvested pancreas and simultaneously contacting the pancreatic β islet cells with a quinolone antibiotic; the method resulting in a xenotransplantable islet.

223.-224. (Canceled)

225. (Currently Amended) A method of preparing a xenotransplantable porcine islet comprising in sequential order the steps of:

(i) harvesting the pancreas of a piglet, the piglet having an age of between -20 to +10 days relative to full term gestation,

~~(ii) exposing the harvested pancreas to nicotinamide,~~

~~(iii) exposing the harvested pancreas to the quinolone antibiotic ciprofloxacin,~~

and

(ii) exposing the harvested pancreas to the quinolone antibiotic ciprofloxacin,

(iii) exposing the harvested pancreas to nicotinamide, and

(iv) extracting pancreatic β islet cells from the harvested pancreas and simultaneously contacting the pancreatic β islet cells with a trauma protecting

agent lignocaine; the method resulting in a xenotransplantable islet.

226. (Currently Amended) A method of preparing a xenotransplantable porcine islet comprising in sequential order the steps of:

(i) harvesting the pancreas of a piglet, said piglet having an age of between -20 to +10 days relative to full-term gestation;

(ii) exposing said harvested pancreas of said piglet to ~~an effective amount of~~ nicotinamide;

(iii) exposing said harvested pancreas to ~~an effective amount of the trauma-protecting agent~~ lignocaine;

(iv) extracting pancreatic β islet cells from said harvested pancreas in the presence of ~~an effective amount of a~~ suitable collagenase ~~human liberase~~; and

(v) contacting said extracted pancreatic β islet cells with ~~an effective amount of a~~ quinolone antibiotic, wherein said method results in the preparation of said xenotransplantable porcine islet.

227. (Currently Amended) A method of preparing a xenotransplantable porcine islet comprising in sequential order the steps of:

(i) harvesting the pancreas of a piglet, said piglet having an age of between -20 to +10 days relative to full-term gestation;

(ii) exposing said harvested pancreas of said piglet to ~~an effective amount of~~ nicotinamide;

- (iii) exposing said harvested pancreas to ~~an effective amount of~~ a trauma-protecting agent;
- (iv) extracting pancreatic β islet cells from said harvested pancreas in the presence of a suitable collagenase~~an effective amount of a human liberase~~; and
- (v) contacting said extracted pancreatic β islet cells with ~~an effective amount of~~ the quinolone antibiotic ciprofloxacin, wherein said method results in the preparation of said xenotransplantable porcine islet.

229. (Currently Amended) The method of any one of claims 212-215, wherein the step of extraction includes the use of a suitable human collagenase ~~liberase~~.

In claim 231, -- claim 230 -- have been inserted in place of "claims 212-215".

Conclusion

Claims 212-215, 222, 225-236 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **William Phillips**, whose telephone number is (571) 272-0548.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

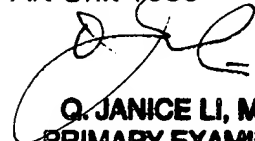
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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QJL
May 2, 2006

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